DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98D–1169]

Guidance for Industry on Content and Format for Geriatric Labeling; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance for industry entitled "Content and Format for Geriatric Labeling." FDA established the "Geriatric use" subsection in the labeling for human prescription drug and biological products to provide pertinent information about the appropriate use of drugs in the elderly (persons aged 65 and over). This guidance is intended to provide industry with information on submitting geriatric labeling for human prescription drug and biological products, including who should submit revised labeling, the implementation schedule, a description of the regulation and optional standard language in the proposed labeling, the content and format for geriatric labeling supplements, and the applicability of user fees to geriatric labeling supplements.

DATES: Submit written or electronic comments on agency guidances at any time.

ADDRESSES: Submit written requests for single copies of this guidance to the Drug Information Branch (HFD–210), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, or to the Office of Communication, Training and Manufacturers Assistance (HFM–40), Center for Biologics Evaluation and Research, Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448. Send one self-addressed adhesive label to assist that office in processing your requests. Submit written comments on the guidance to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to http://www.fda.gov/

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dockets/ecomments. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT: Mary E. Ortuzar, Center for Drug Evaluation and Research (HFD–006), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–6740; or Toni Stifano, Center for Biologics Evaluation and Research (HFM–600), 1401 Rockville Pike, Rockville, MD 20852, 301–827–6190.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry entitled "Content and Format for Geriatric Labeling." This guidance has been developed in response to a final rule that published in the **Federal Register** of August 27, 1997 (62 FR 45313), establishing, in the "Precautions" section of prescription drug labeling, a subsection on the use of drugs in elderly or geriatric patients (aged 65 years or over) (§ 201.57(f)(10) (21 CFR 201.57(f)(10))). A draft guidance by the same name was made available for comment by a notice published in the **Federal Register** of January 21, 1999 (64 FR 3302). This guidance incorporates minor revisions based on comments the agency received on the draft guidance. The final guidance makes clear that the application holder is responsible for submitting a supplement to request the omission of the "Geriatric use" subsection or to request an alternative statement and for providing the reasons supporting the request.

The geriatric labeling regulation recognizes the special concerns associated with the geriatric use of prescription drugs and acknowledges the need to communicate important information so that drugs can be used safely and effectively in older patients. The medical community has become increasingly aware that prescription drugs can produce effects in the elderly that are significantly different from those produced in younger patients. Geriatric labeling information is of increasing importance because of the growing proportion of the population that is over 65 years of age and the significant use of medications by this age group.

This guidance discusses which application holders are responsible for submitting revised labeling and summarizes the implementation schedule for submitting geriatric labeling. The geriatric labeling regulation includes six paragraphs (§ 201.57(f)(10)(i) through (f)(10)(vi)) that outline various options for statements in the "Geriatric use" subsection, based on the type of information available and the interpretation of that information. The guidance summarizes the requirements of § 201.57(f)(10)(i) through (f)(10)(vi) and provides detailed guidance on the submission of this information. In addition, the content and format for geriatric labeling supplements, as well as the applicability of user fees to geriatric labeling supplements, are discussed in detail in the guidance document.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the agency's current thinking on the content and format of geriatric labeling. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

II. Comments

Interested persons may, at any time, submit written or electronic comments on the guidance to the Dockets Management Branch (address above). Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. The guidance and received comments are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

III. Electronic Access

Persons with access to the Internet may obtain the document at either http://www.fda.gov/cder/guidance/index.htm or http://www.fda.gov/cber/guidelines.htm.

Dated: 9/28/01

September 28, 2001.

Margaret M. Dotzel,
Associate Commissioner for Policy.

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